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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,104	09/27/2004	Shingo Kawasaki	983.4426X00	1276

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ANTONELLI, TERRY, STOUT & KRAUS, LLP  
1300 NORTH SEVENTEENTH STREET  
SUITE 1800  
ARLINGTON, VA 22209-3873

EXAMINER

BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/509,104	KAWASAKI, SHINGO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Etsub D. Berhanu	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7 is/are rejected.
- 7) ☒ Claim(s) 6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/27/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/27/2004</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 4 is objected to because of the following informalities: line 4 should be amended to read -- includes at least one of a hemoglobin variation pattern --. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1 recites the limitation "the same" in line 9. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 3 recites the limitation "the same" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 5 recites the limitation "the same" in lines 7 and 16. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita et al.'309 (US Patent No. 6,240,309).

Figure 28 of Yamashita et al.'309 discloses a biological photometer comprising light sources 1-1 and 1-2 which generate light having a predetermined wavelength in a region from visual to infrared (col. 31, lines 45-48), optical fibers 2-1, 2-2, 8-1 and 10-1, a photometer unit 11-1 and a signal processing unit 30. The photometer unit detects light irradiated from the optical fibers and produces a hemoglobin signal corresponding to hemoglobin density inside a subject and the signal processing unit prepares hemoglobin variation information of the subject based on the hemoglobin signal and displays the variation information (col. 32, lines 10-65). Figures 28 and 29 of Yamashita et al.'309 indicate that a total hemoglobin concentration variation signal (c) is produced. Figure 34 of Yamashita et al.'309 further discloses that the signal processing unit integrates values of total hemoglobin concentrations at arbitrary time intervals, is capable of determining rates of changes in the total hemoglobin concentrations measured and also contains a judgment unit which the characteristics of the hemoglobin variation pattern at a detection point of the subject with reference values stored in memory (col. 35, lines 41-57). Yamashita et al.'309 also discloses a memory unit (Figure 33, element 130) that is capable of storing characteristics of hemoglobin variation patterns of normal health and a variety of diseases (col. 35, lines 1-15). In its broadest interpretation, the term "diseases" is taken to mean a condition of abnormal functioning. Col. 39, line 33 – col. 41, line 7 discloses the use of the biological photometer of Yamashita et al.'309 in order to determine sensitive states in a driver such as doze, fatigue, redout and blackouts. These conditions would render a driver unable to function normally. Lines 24-29 of col. 41 specifically indicate that the apparatus of Yamashita et al.'309 is capable of being used as a diagnostic and warning device for determining the focus of epilepsy and functional brain activity in patients with cerebral diseases.

***Allowable Subject Matter***

9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, a biological photometer comprising either: a judgment unit that determines a correlation coefficient between a hemoglobin variation pattern curve of a hemoglobin variation pattern at a detection portion of a subject with a hemoglobin variation pattern curve in a reference template of normal health and a variety of diseases at the same detection portion stored in a memory unit; or a signal processing unit that modifies the reference template of the normal health and variety of diseases stored in the memory unit by making use of the characteristics of the hemoglobin variation pattern at the detection portion of the subject extracted by the characteristic extraction unit and the judgment result by the judgment unit whether the subject is in normal health or any one of the diseases based on the characteristics, in combination with the other claimed elements.
10. Claims 6 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ozaki et al.'418 (US Patent No. 5,564,418) discloses a diagnostic device that calculates and displays concentration changes in hemoglobin, wherein the device contains time measuring means which integrate a change in the concentration of hemoglobin and which detects a maximum change in concentration of hemoglobin. Cerebral blood volume and cerebral blood flow are determined as a result of the hemoglobin concentration calculations.


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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB



ERIC F. WINAKUR  
PRIMARY EXAMINER